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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,905	11/13/2003	Charles R. Stomberg	P-20003.00	9463

27581 7590 03/29/2007

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EXAMINER	
LUSTUSKY, SARA	
ART UNIT	**PAPER NUMBER**
3735	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,905	STOMBERG ET AL.	
	Examiner	Art Unit	
	Sara Lustusky	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-11,13,14,19,22 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-11,13,14,19,22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 March 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The Examiner acknowledges Applicant's Amendment dated March 12, 2007. Claims 1, 10, 19 have been amended. Claims 2-3, 12, 15-18 and 20-21 are cancelled. Claims 1, 4-11, 13-14, 19 and 22-23 are pending.

Drawings

The drawings were received on March 12, 2007. These drawings are acceptable and in view of Applicant's amendments to the drawings, the drawing objections set forth in the Office Action dated December 11, 2006 are withdrawn.

Claim Objections

In view of Applicant's amendments to the claims, the claim objections set forth in the Office Action dated December 11, 2006 are withdrawn.

Claim 9 is objected to because of the following informalities: Claim 9 does not show the proper claim status notation (i.e. Original, Amended, etc.). Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-9, 19 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoyama et al. (US 5921938 A) in view of Goedeke (US 5904708 A) and further in view of Karam et al. (US 2003/0161321 A1).

Aoyama et al. teaches a method comprising:

a. detecting a first time output from the clock of an implantable medical device at a first time, detecting a first time output from a reference clock at the first time; detecting a second time output from the clock of the implantable medical device at a second time, detecting a second time output from the reference clock; and calculating the drift based on the difference between the second time output from the clock of the implantable medical device and the second time output from the reference clock (as described in claims 1-2, 5, 6, 8, 10-16 and 26);

b. generating a correction factor to correct for the drift and correlating time data from the clock to a reference time frame by correcting for the drift (as described in lines 6-21 of column 7 and in lines 42-45 of column 8 describing an alternate embodiment);

c. wherein the time data is received at a programmer and then correlated (as described in lines 25-37 of column 7);

d. programming the implantable medical device with the correction factor (as described in claims 5, 8 and 11);

e. wherein identifying lost time includes identifying periods of therapy delivery (as described in lines 40-45 of column 1 and in lines 9-15 of column 8);

f. wherein correcting includes modifying data from the implantable medical device with a positive or negative time difference so that time is added or subtracted from the data temporally proximate wherein the time was lost or gained (as seen in Figures 2B and 3);

g. wherein the method instructions are contained on a computer readable medium that when executed on an electronic device, causes the electronic device to perform functions according to the instructions (as described in lines 1-63 of column 4 and in lines 26-34 of column 5);

h. wherein the programmer comprises a communication link communicatively coupleable to a medical device capable of receiving time data from the device, a reference clock providing reference time data, and a calibrating module that receives the device time data and the reference time data, measures drift in the device data and generates a correction factor (as described in lines 6-20 and 31-44 of column 7); and

i. wherein the calibrating module is operatively coupled with the communication link so that the correction factor is programmed into the device, wherein the correction factor may be determined by an algorithm indicating a positive or negative time difference (as described in claims 1-2, 5, 6, 8, 10, 12-13, 15 and 26).

While Aoyama et al. teaches that the medical device may be a defibrillator or a monitor having a clock, implantable devices are not expressly taught nor is it expressly taught that the clock is an oscillator.

Goedeke teaches time synchronization of a clock (138) of an implantable medical device (100) with an external reference clock (as described in lines 52-62 of column 9), wherein the implantable medical device (100) may be a defibrillator (as described by the embodiment in lines 19-26 of column 1). Goedeke further teaches that the clock (138) of the implantable device (100) is an oscillator (138) (as described in lines 28-29 of column 10) (as seen in Figures 1 and 2) connected to a circuit having a programming means for

correlating the frequency to a standard time format (as described in lines 49-65 of column 10).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a method similar to that of Aoyama et al. to synchronize the clock of an implantable medical device similar to the method of Goedeke in order to ensure that the data received from the implantable medical device accurately reflects the sequence of treatment or use of the implantable medical device which directly reflects and/or indicates the health of the patient. Furthermore, electronic clocks comprising crystals or oscillators were commonly used in implantable devices at the time of the invention.

While the combination of Aoyama et al. and Goedeke teaches a method comprising applying corrections means to a clock of an implantable device based on the calculated amount of drift between said clock of said implantable device and a reference clock, it does not teach that the correction means comprises determining the slope of a difference between the timelines obtained for the clock of the implantable device and that for the reference clock.

Karam et al. teaches a method of synchronizing a clock time associated with incoming data and the time of a reference clock in order to ensure an accurate time stamp is applied to said incoming data, wherein Karam et al. teaches a variety of mechanisms by which to synchronize the times of said clocks (as described in paragraphs [0249]-[0260]), said mechanisms comprising generating a correction factor to correct for the drift and correlating time data from the clock to a reference time frame by correcting for the drift, wherein the time data is received at a programmer and then correlated, and wherein correcting includes modifying data from the implantable medical device with a positive or negative time difference so that time is added or subtracted

from the data temporally proximate wherein the time was lost or gained and wherein the drift may be calculated by determining a slope of a divergence between the timelines of said clocks (as described in paragraph [00254]).

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to calculate drift in a method similar to that of the combination of Aoyama et al. and Goedeke by calculating the slope of the divergence between the timeline of a clock associated with a device and the timeline of a reference clock in view of the teachings of Karam et al. because using the slope of the divergence between the two clock timelines and making frequent corrections using the difference between the two clocks are functionally equivalent ways of synchronizing the clock times. One of ordinary skill in the art, furthermore, would have expected the method of the combination of Aoyama et al. and Goedeke, and applicant's invention, to perform equally well.

Therefore, it would have been prima facie obvious to modify the combination of Aoyama et al. and Goedeke to obtain the invention as specified in claim 1 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of this combination.

Claims 10-11 are rejected under 35 U.S.C. 35 U.S.C. 103(a) as being unpatentable over Aoyama et al. (US 5921938 A) in view of Morohoshi et al. (US 6219303 B1).

Aoyama et al. teaches an apparatus comprising communication means capable of communicating with and receiving time data from an implantable medical device, measuring means capable of determining an amount of drift or lost time in the time data relative to a reference time, and correction means capable of correcting the data by

removing the drift, which may be a positive or negative time difference, so that the corrected data correlates to the reference time (as described in lines 1-12 of the abstract and in claims 1-2, 5, 6, 8, 10, 12-13, 15 and 26).

However, Aoyama et al. does not teach that said apparatus comprises a means for modifying the time data to eliminate time differences due to time zone variations.

Morohoshi et al. teaches a clock and a time correction method comprising communication means capable of determining an amount of drift of said clock and a reference clock and correction means capable of correcting the time of said clock by removing the drift, which may be a positive or negative time difference, further comprising means for determining the differences between the clock time and the reference time due to time zone variations and means for modifying the time of said clock to eliminate the differences due to time zone variations (as described in the abstract and in lines 54-67 of column 1, lines 1-15 of column 2, lines 8-30 of column 4) (as seen in Figures 4, 6 and 15-16).

It would have been obvious to one having ordinary skill in the art at the time of the invention to combine an apparatus similar to that of Aoyama et al. with a means for modifying the time data to eliminate the differences due to time zone variations between a reference clock and that of the apparatus clock in order to increase the accuracy of said time data (as described in lines 8-15 of column 2 of Morohoshi et al.).

Claims 10 and 14 are rejected under 35 U.S.C. 35 U.S.C. 103(a) as being unpatentable over MacDuff et al. (US 6041257 A) in view of Morohoshi et al. (US 6219303 B1).

MacDuff et al. teaches an apparatus comprising communication means capable of communicating with and receiving time data from an implantable medical device,

measuring means capable of determining an amount of drift or lost time in the time data relative to a reference time, and correction means capable of correcting the data by removing the drift or lost time so that the corrected data correlates to the reference time (as described in lines 45-62 of column 3 and in lines 17-34 and 41-45 of column 6); wherein the apparatus is capable of simultaneously synchronizing time data from multiple implantable medical device to the reference time (as described in lines 20-22 of column 13 and in lines 8-21 of column 14).

However, MacDuff et al. does not teach that said apparatus comprises a means for modifying the time data to eliminate time differences due to time zone variations.

Morohoshi et al. (US 6219303 B1) teaches a clock and a time correction method as described above, comprising means for determining the differences between the clock time and the reference time due to time zone variations and means for modifying the time of said clock to eliminate the differences due to time zone variations (as described in the abstract and in lines 54-67 of column 1, lines 1-15 of column 2, lines 8-30 of column 4) (as seen in Figures 4, 6 and 15-16).

It would have been obvious to one having ordinary skill in the art at the time of the invention to combine an apparatus similar to that of MacDuff et al. with a means for modifying the time data to eliminate the differences due to time zone variations between a reference clock and that of the apparatus clock in order to increase the accuracy of said time data (as described in lines 8-15 of column 2 of Morohoshi et al.).

Claims 10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Aoyama et al. (US 5921938 A), Goedeke (US 5904708 A) and Karam et al. (US 2003/0161321 A1) as applied to claim 1 above, further in view of Morohoshi et al. (US 6219303 B1).

The combination of Aoyama et al., Goedeke and Karam et al. teaches an apparatus comprising communication means, measuring means and correction means for correlating time data from a implantable medical device and synchronizing the time of a clock of said implantable medical device and a reference clock, as described above, but does not teach that said apparatus comprises a means for modifying the time data to eliminate time differences due to time zone variations.

Morohoshi et al. (US 6219303 B1) teaches a clock and a time correction method as described above, comprising means for determining the differences between the clock time and the reference time due to time zone variations and means for modifying the time of said clock to eliminate the differences due to time zone variations, as described above.

It would have been obvious to one having ordinary skill in the art at the time of the invention to combine an apparatus similar to that of the combination of Aoyama et al., Goedeke and Karam et al. with a means for modifying the time data to eliminate the differences due to time zone variations between a reference clock and that of the apparatus clock in order to increase the accuracy of said time data (as described in lines 8-15 of column 2 of Morohoshi et al.).

Response to Arguments

Applicant's arguments with respect to claims 1-23 have been considered but are moot in view of the new ground(s) of rejection. Applicant contends that the claims have been amended to be consistent with the Examiner's indication of allowable subject matter. However, the indicated allowability of claims 3, 12 and 21 is withdrawn in view of the newly discovered reference(s) to Karam et al., Goedeke and Morohoshi et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sara Lustusky whose telephone number is (571) 272 8965. The examiner can normally be reached on M-F: 9 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272 4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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